

### **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 14-29 will be pending in the application subsequent to entry of this Amendment.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and to include in new claims 27-29 directed to embodiments of the invention which have not been specifically claimed.

The restriction requirement has been maintained, the examiner asserting that applicants' composition contains the same components in the same configuration as the prior art and argues that the properties would be the same when the structure and composition are the same. As explained in the remarks that follow, as well as the attached evidentiary declaration, this is not the case and applicants again request that the requirement for restriction be withdrawn after the examiner takes into account the wording of the claims as now presented and the evidence of the type specifically requested by the examiner presented herewith.

The sole issue raised in the Official Action is the patentability of previous claim 1 which the examiner alleges to be anticipated by WO 97/11682 to Liu. To the extent this reference is thought to pertain to new claim 14 this rejection is respectfully traversed.

As noted in the response to the Restriction Requirement, there are two key limitations to applicants' claims in this case. The first is compositional, and the second functional (relating to the phase behavior). Thus, although the compositional restriction is "open", using "comprising" language, the claimed compositions are severely restricted because they must also show the functional restriction of appropriate phase behavior (forming or generating a non-lamellar phase).

In the response to the Restriction requirement, applicants stated that the compositions of Liu would not exhibit the required phase behavior, since although the ratio of DOPE to P80 is correct, there is an overwhelmingly greater amount of other material which would swamp the effect of these components. The Examiner has requested that applicants show "unexpected results" with the compositions of the application over Formulation 17 on page 29 of Liu. This formulation contains 1:1 DOPE:P80, thus falling within the composition limitations of claim 14, but also contains 1 part castor oil and 3 parts DC-Chol. The Examiner indicated that a

declaration would be suitable to overcome this rejection. Applicants are pleased to accommodate the examiner's request.

In the attached declaration, inventor Tiberg confirms that the phase behavior of mixtures of DOPE and P80 has been studied in his laboratory and found to be markedly affected by the addition of other components in significant amounts. In particular, since DOPE and P80 each amount to only around 16% of the composition, these would be in an amount insufficient to convert the composition of castor oil and DC-Chol to a non-lamellar phase. Thus, composition #17 of Liu does not disclose any composition meeting the limitations of the present claims in terms of phase behavior. Furthermore, since Liu explicitly aims to generate emulsion and micellar compositions, which are not non-lamellar compositions according to the present invention, there is no teaching to suggest that such non-lamellar compositions are obtainable from DOPE and P80. Thus it cannot be seen as obvious to provide the compositions of the present invention.

In view of the attached declaration and above discussion, applicants submit that it is clear that claim 14 is patentable. The issue then arises as to which other claims might be rejoined with this independent claim. In particular, since all of claims 17 to 26 are dependent upon claim 14, no additional examination is required to determine that these claims must also be patentable.

Applicants request that these claims be rejoined. Furthermore, independent claims 15 and 16 also contain all of the restrictions of claim 14, with the addition of an optional solvent and limitations with regard to toxicity. Thus, these claims should also be rejoined, but if this is not possible and the other claims are allowed, the examiner is authorized to delete these claims.

In addition to the above, please note additional claim 21, dependent upon claim 14, in which the composition of 50:50 DOPE:P80 is no longer within the claim. With this restriction, it is evident that Liu satisfies neither the compositional nor functional (phase behavior) limitations of the claim. Also included are corresponding claims dependent upon original claims 15 and 16.

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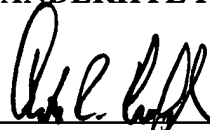
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For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

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